DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

MedicaTech USA
% Daniel Kamm, P. E.
Principal Engineer
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

February 6, 2015

Re: K143257
Trade/Device Name: KrystalRad 1100 and KrystalRad 3000 Digital Stationary Radiographic Systems
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR, MQB
Dated: January 13, 2015
Received: January 15, 2015

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143257

Device Name
KrystalRad 1100 and KrystalRad 3000 Digital Stationary Radiographic Systems

Indications for Use *(Describe)*
The KrystalRad 1100 and KrystalRad 3000 Digital Stationary Radiographic Systems are intended for use by a qualified/ trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest. abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) Summary, 510(k) K143257

Submitter: MedicaTech USA
50 Maxwell
Irvine , CA , 92618
Toll Free : +1 800 817 5030
Phone : +1 949 679 2881
FAX : +1 949 679 2882
Registration Number 3004989804
Contact: George Makar, Predsident
Date Prepared: August 21, 2014

1. Identification of the Device:
   Proprietary-Trade Name: KrystalRad 1100 and KrystalRad 3000 Digital Stationary Radiographic Systems
   Classification Name: Stationary X-Ray System, Product codes KPR and MQB
   Common/Usual Name: Digital Diagnositc X-Ray System
   Device Class: II per regulation 21CFR892.1680

2. **Equivalent legally marketed device: K133782, Sedecal Nova FA DR System, Sedecal SA.**

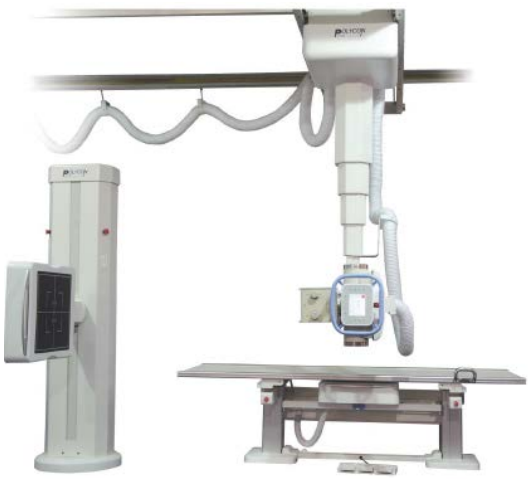
3. **Indications for Use** The KrystalRad 1100 and KrystalRad 3000 Digital Stationary Radiographic Systems are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest. abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography.

4. **Description of the Device**: This device represents a new combination of already cleared solid state digital x-ray acquisition panels and software with the diagnostic x-ray compnents required to make a complete system. The purchaser may select their digital panel from this list:
   - Toshiba wireless flat panel detector (FDX-3543RP, FDX-3543RPW, 14 in. x 17 in.) or Toshiba wired flat panel detector (FDX-4343R, 17 in x l7in). (K130883)
   - Vieworks all series: (FXRD-1717SA/SB, or FXRD-1417SA/SB or FXRD-1417WA/WB. (K130337, Medicatech "New Series.")
   - PerkinElmer XRpad™ 4336 MED, (K140551).

   The purchaser can select either a "C" arm configuration (KrystalRad 1100) or an overhead tube crane configuration (KrystalRad 3000). Please see the photos below. The x-ray generator is a CPI CMP 200DR. The x-ray tubes are supplied by Toshiba (E7252X Series), and the collimator is the Ralco R302A. An IBA kerma meter model 120-131 is supplied. The system complies with the CDRH Radiological Health performance standard in the Code of Federal Regulations, as well as the voluntary IEC standards IEC 60601-1 and IEC 60601-1-2. The generator complies with IEC 60601-2-54.

5. **Safety and Effectiveness, comparison to predicate device**. This combination device has the same indications for use and very similar technological characteristics as the predicate device, and employs already 510(k) cleared digital panels and software.

6. **Substantial Equivalence Chart: Please see the next page.**

Characteristic	Sedecal Nova FA K133782	KrystalRad 1100 and KrystalRad 3000
Intended Use:	Sedlecal "NOVA FA DR System" is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest. abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography.	KrystalRad 1100 and KrystalRad 3000 are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest. abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography.
Configuration of Digital Panels	Battery or AC operated wireless IEEE 802.11n or Wired Ethernet	SAME
Digital Panel Models and their clearance numbers	CXDI Canon Detector 401C/401C Compact (K103591) CXDI Canon Detector 55C (K091436) CXDI Canon Detector 501C (K111682)	Vieworks/Medicatech FXRD-1717SA/SB, FXRD-1417SA/SB and FXRD-1417WA/WB (K130337) Toshiba: FDX4343R/RPW, FDX3543RP and FDX3543RPW (Del Medical: K140825; O&R: K131121; Sedecal: K130883) PerkinElmer: XRpad 4336 MED (K140551)
Image acquisition panel specifications	3,320 x 3,408 125 µm (401C) or 2,208 x 2,688 pixels 160 µm (55C) 2,800 x 3,408 Pixels 125 µm (501C)	FXRD-1717SA/SB: 3,072 x 3,072, 140µm FXRD-1417SA/SB: 2560 x 3072, 140µm FXRD-1417WA/WB: 2560 x 3072, 140µm FDX4343R/RPW: 3008×3072, 143 µm FDX3543RP: 2448×2984, 143 µm FDX3543RPW: 2466×3040, 140µm XRpad 4336 MED: 3556×4320, 100 µm
DICOM	DICOM 3	DICOM 3
WiFi Wireless IEEE802.11n (All others are Ethernet Tethered.	Not applicable, but compatible with all Canon panels, including wireless.	Vieworks FXRD-1417WA/WB Toshiba FDX3543RPW PerkinElmer XRpad 4336 MED
Image acquisition software	CANON cleared in K111682	CrystalRad as cleared in K130377
Power Source	AC Line, various voltages available	SAME
Photo		Krystalrad 3000 

Characteristic	Sedecal Nova FA K133782	KrystalRad 1100 and KrystalRad 3000
Alternate configuration	Sedecal X-Plus LP Plus, K090238 	KrystalRad 1100 
Generator	Sedecal SHF	CPI CMP 200DR
Collimator	Ralco R225A	Ralco R301A
Performance Standard	FDA 21CFR1020.30-31	SAME
Electrical safety	Electrical Safety per IEC-60601. UL listed	SAME

7. **Summary of non-clinical testing**: We performed integration testing. The results of a review of bench, safety test, and software validation documentation indicates that the new device is as safe and effective as the predicate device. The device conforms to US Performance Standards and the hardware is UL Listed to US Standards for safety for medical devices (UL 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety standard by Underwriters Laboratories, 04/25/2003.) All of the panels comply with NEMA PS 3.1 - 3.18 (2009) Digital Imaging and Communications in Medicine (DICOM) Set. Successful testing according to 60601-2-54 standard had been performed on the CPI generator.

8. **Summary of clinical testing**: Clinical images were acquired from each panel and reviewed by a board certified radiologist. The images were found to be of excellent diagnostic quality.

9. **Conclusion:** After analyzing software integration validation, safety testing data, and clinical images, it is the conclusion of Medicatech USA that the "KrystalRad 1100 and KrystalRad 3000" are as safe and effective as the predicate device, have few technological differences, and has identical indications for use, thus rendering it substantially equivalent to the predicate device. "Technological differences from the predicate device include different detectors, some with wireless functionality, a different system generator, and collimator. Although the components differ from the primary predicate device, the detectors and other components have been cleared as part of other 510(k) submissions as noted in this 510(k) Summary. Integration testing, including acquisition of phantom images, demonstrated that the hardware and software components work properly together.